



CHEMICAL MANUFACTURERS ASSOCIATION

COURTNEY M. PRICE
VICE PRESIDENT
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November 30, 1998

Via Facsimile (919/541-0295)

Dr. Larry G. Hart
Executive Secretary
Board of Scientific Counselors
National Toxicology Program
P.O. Box 12233
Research Triangle Park, NC 27709

RE: Draft RoC Background Document for Ethylene Oxide

Dear Dr. Hart:

The Olefins Panel (Panel) of the Chemical Manufacturers Association (CMA) submits these comments on the Draft RoC Background Document for Ethylene Oxide (Draft EO Document), prepared for the December 2 and 3, 1998 meeting of the Report on Carcinogens (RoC) Subcommittee of the National Toxicology Program (NTP) Board of Scientific Counselors. See 63 Fed. Reg. 57132 (Oct. 26, 1998). Members of the Olefins Panel include the major domestic producers and importers and some users of 1,3-butadiene (butadiene).¹ The Draft EO Document includes statements comparing ethylene oxide to butadiene. Assertions in the Draft EO Document concerning epidemiological data for butadiene should be deleted or substantially revised.

The Draft EO Document states that occupational exposure to 1,3-butadiene "has been consistently associated with excess mortality from lymphatic and hematopoietic cancers."² No citation is given for that assertion. However, the language is essentially that of the draft background document on 1,3-butadiene that was prepared for the October 30, 1997 meeting of the RoC Subcommittee.³ The assertion that butadiene has been consistently associated with occupational cancer mortality has been challenged in comments submitted to NTP, and the NTP Executive Committee and Director have not yet reviewed that issue. Moreover, each page of the Draft BD Document states, "DRAFT PROPOSED RC LISTING FOR 1,3-BUTADIENE--DO

¹ Members of the Olefins Panel include: Asahi Chemical Industries, America; BP Chemicals, Inc.; Chevron Chemical Company; The Dow Chemical Company; DuPont; Eastman Chemical Company; Equistar Chemicals, LP; Exxon Chemical Americas; Huntsman Corporation; Shell Chemical Company; and Union Carbide Corporation.

² Draft EO Document at RoC-3, 6-6.

³ "[S]tudies in humans . . . have consistently found excess mortality from lymphatic and hematopoietic cancers associated with occupational exposure to butadiene . . ." NTP, *RC Draft Background Document for 1,3-Butadiene*, page RC-1 (Sept. 29, 1997) [Draft BD Document].



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NOT QUOTE OR CITE.” Therefore, it is inappropriate to use that assertion to support the NTP’s draft findings on ethylene oxide.

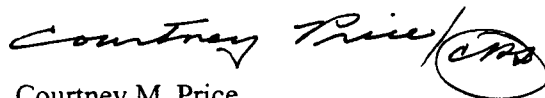
Furthermore, the conclusion of other scientific bodies that have recently reviewed butadiene epidemiology studies is that the data are not consistent. In February 1998, the International Agency for Research on Cancer (IARC) carefully reviewed butadiene and concluded that “the published evidence does not allow consistency of findings to be evaluated among two or more studies of adequate statistical power, and the epidemiological evidence was thus evaluated as limited.”⁴

Similarly, on April 29 and May 30, 1998, the Environmental Health Committee of EPA’s Science Advisory Board (SAB) reviewed EPA’s draft Health Risk Assessment of 1,3-Butadiene. The SAB found “lack of consistency between exposure response rates for leukemia or lymphosarcoma when both the styrene-butadiene (SBR) and monomer worker studies were considered in total.”⁵ The SAB report explains that it is not appropriate to lump lymphatic and hematopoietic cancers,⁶ and that: “The majority felt that there were conflicting results among SBR and monomer workers for leukemia and a lack of compelling evidence for a relationship between lymphosarcoma and butadiene exposure.”⁷

An NTP representative was a participant at the IARC review, and an NTP representative was an invited expert at the SAB review. Therefore, NTP should be aware that the view that the epidemiological evidence for butadiene is consistent was presented at those reviews, but was not accepted by those bodies. In light of the IARC and SAB conclusions and the comments submitted on the Draft BD Document, NTP should delete from the Draft EO Document the assertion that occupational exposure to butadiene has been consistently associated with lymphatic and hematopoietic cancers. If NTP retains any discussion of butadiene in the Draft EO Document at all, it should discuss the inconsistency of the findings for SBR and monomer workers.

If you have any questions, please call Dr. Elizabeth J. Moran, Director of the Olefins Panel, at (703) 741-5617.

Sincerely yours,



Courtney M. Price
Vice-President, CHEMSTAR

⁴ IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, *Re-evaluation of Some Industrial Chemicals (Vol. 71) (17-24 February 1998)* (Summary provided on the Internet, <http://193.51.164.11/htdocs/announcements/vol71.htm>, Mar. 18, 1998).

⁵ EPA, *An SAB Report: Review of the Health Risk Assessment of 1,3-Butadiene*, page 2 (EPA-SAB-EHC-99-003, Nov. 1998).

⁶ *Id.* at 21 and 46.

⁷ *Id.* at 32.